Not for Publication

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

UNITED STATES OF AMERICA *ex rel.* CHARLES L. BENNETT, **Plaintiff-Relator,** **v.** **BAYER CORPORATION, *et al.*,** **Defendants.**	**Civil Action No.: 17-4188 (ES) (JBC)** **OPINION**

SALAS, DISTRICT JUDGE

In this *qui tam* action, Relator Charles L. Bennett sues Defendants Bayer Corporation and Merck & Co., Inc. (together, "Bayer"), and Defendant Johnson & Johnson Corporation ("J&J")[1] alleging claims under the False Claims Act ("FCA"), 31 U.S.C. § 3729 *et seq.* and similar state laws (D.E. No. 59 ("Second Amended Complaint" or "SAC")). Relator claims that Bayer and J&J violated the FCA and similar state laws by intentionally misleading the federal government to get approval to market, sell, and profit from two fluoroquinolone antibiotics ("FQs"), resulting in medical providers prescribing the FQs and seeking fraudulently-induced reimbursements from federal and state healthcare payors. (SAC ¶¶ 1–10). Bayer and J&J each move separately to

[1] Relator also brought claims against Johnson & Johnson Pharmaceutical Research & Development LLC. and Ortho-McNeil-Janssen Pharmaceuticals, Inc. (SAC). On March 14, 2024, this Court entered a Notice of Call for Dismissal pursuant to L. Civ. R. 41.1(a) as to Defendants Johnson & Johnson Pharmaceutical Research & Development LLC. and Ortho-McNeil-Janssen Pharmaceuticals, Inc. (D.E. No. 92). On March 21, 2024, Relator filed a Notice of Voluntary Dismissal as to Defendants Johnson & Johnson Pharmaceutical Research & Development LLC. and Ortho-McNeil-Janssen Pharmaceuticals, Inc. The Court granted Relator's request for partial dismissal as to these defendants. (D.E. No. 94). The Court's opinion, therefore, applies to the active Parties in this matter—Relator Charles L. Bennett and Defendants Bayer Corporation, Merck & Co., Inc., and Johnson & Johnson Corporation.

dismiss the Second Amended Complaint. (D.E. Nos. 71 ("Bayer Mov. Br.") & 68 ("J&J Mov. Br."); *see also* (D.E. Nos. 84 & 83). Having considered the Parties' submissions, the Court decides both Motions without oral argument. *See* Fed. R. Civ. P. 78(b); L. Civ. R. 78.1(b). For the reasons set forth below, Defendants' Motions are **GRANTED**. The Second Amended Complaint is dismissed *with prejudice*.

I. BACKGROUND

A. Factual Background

Before marketing and selling a new drug, pharmaceutical manufacturers must submit and obtain approval from the U.S. Food and Drug Administration ("FDA") of a New Drug Application ("NDA"). 21 U.S.C. §355(a); *see also* (SAC ¶ 49). In 1985, Bayer submitted an NDA for "Ciprofloxacin, an FQ, [2] which it branded and sold as 'Cipro.'" (*Id.* ¶ 4; *see also* Bayer Mov. Br. at 4). The FDA approved Cipro in 1987 (SAC ¶ 28), after a multi-year review. (Bayer Mov. Br. at 4).

Similarly, J&J developed an FQ, Levofloxacin, in the 1990s. (J&J Mov. Br. at 3). On February 11, 1992, J&J presented a "proposed clinical development plan for Levofloxacin." (*Id.*). After the FDA reviewed J&J's submission, the FDA provided feedback and "J&J submitted a revised plan on April 29, 1994." (*Id.*). Throughout the development of Levofloxacin, "J&J and the FDA engaged in communication relat[ed] to the parameters of clinical trials" in support of the NDA for Levofloxacin. (*Id.*). On December 21, 1995, J&J submitted the NDA for Levofloxacin which, after approval on December 20, 1996, J&J marketed and sold as Levaquin. (*Id.* at 3–4; SAC ¶ 5).

[2] FQs "are an antibiotic class of medicines used to treat bacterial infections." (SAC ¶ 41). "FQs have a distinct molecular structure . . . in order to increase the efficacy and utility of the drug as an anti-microbial agent" to destroy microbes. (*Id.* ¶ 42).

In 2006, Dr. Sydney Wolfe, among others, conducted independent research and discovered "a serious and previously publicly undisclosed side-effect of FQs—acute rupturing of the Achilles tendon." (SAC ¶ 70). Dr. Sydney, together with Dr. Jay Parkinson, submitted a letter to the acting commissioner of the FDA requesting that the FDA "immediately add a black box warning regarding the risks of tendinopathy and tendon rupture to the product labels of all fluoroquinolone antibiotics presently on the market in the United States." Letter from Jay Parkinson, M.D., M.P.H., Rsch. Analyst, & Sidney M. Wolfe, M.D., Dir., Pub. Citizen's Health Rsch. Group, to Andrew Von Eschenbach, M.D., Acting Comm'r, U.S. Food and Drug Admin. (Aug. 26, 2006); https://www.citizen.org/article/petition-for-a-black-box-warning-on-fluoroquinolone-antibiotics; (SAC ¶ 70). After the submission of this letter, on July 8, 2008, the FDA published an alert for "Healthcare Professionals" concerning "Fluoroquinolone Antimicrobial Drugs [ciprofloxacin (marketed as Cipro and generic ciprofloxacin), ciprofloxacin extended-release (marketed as Cipro XR and Proquin XR), gemifloxacin (marketed as Factive), levofloxacin (marketed as Levaquin), moxifloxacin (marketed as Avelox), norfloxacin (marketed as Noroxin), and ofloxacin (marketed as Floxin)]." *Information for Healthcare Professionals: Fluoroquinolone Antimicrobial Drugs [Ciprofloxacin (Marketed as Cipro and Generic Ciprofloxacin), Ciprofloxacin Extended-Release (Marketed as Cipro XR and Proquin XR), Gemifloxacin (Marketed as Factive), Levofloxacin (Marketed as Levaquin), Moxifloxacin (Marketed as Avelox), Norfloxacin (Marketed as Noroxin), and Ofloxacin (Marketed as Floxin)]*, U.S. FOOD AND DRUG ADMIN. (Aug. 15, 2023), https://wayback.archive-it.org/7993/20161022101528/http:/www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm126085.htm. In the Alert, the FDA provided that it was "notifying the makers of fluoroquinolone antimicrobial drugs for systemic use of the need to add a boxed warning to the prescribing information about the increased risk of

developing tendinitis and tendon rupture in patients taking fluoroquinolones and to develop a Medication Guide for patients. The addition of a boxed warning and a Medication Guide would strengthen the existing warning information already included in the prescribing information for fluoroquinolone drugs." *Id.* The FDA provided additional recommendations and information for healthcare professionals to consider regarding FQs and shared information for healthcare professional to provide when counseling patients. *Id.* The FDA provided the following background information:

> A warning about the increased risk of tendinitis and tendon rupture in patients taking fluoroquinolones was previously added to the prescribing information for fluoroquinolones. However, FDA's recent evaluation of the medical literature and the post-marketing adverse event reports submitted to the Adverse Events Reporting System (AERS) confirmed that serious reports of tendinitis and tendon rupture with the fluoroquinolones continue to be reported in similar or increased numbers.
>
> Tendinitis and tendon rupture most frequently involves the Achilles tendon, and rupture of the Achilles tendon may require surgical repair. Tendinitis and tendon rupture in the rotator cuff (the shoulder), the hand, the biceps, and the thumb have also been reported. The risk of developing fluoroquinolone-associated tendinitis and tendon rupture is especially increased in patients over 60 years, in those concomitantly taking corticosteroid drugs, and in patients with kidney, heart or lung transplants. Tendon rupture can occur during or after completion of fluoroquinolone use; cases occurring up to several months after completion of therapy have been reported.
>
> Tendon rupture is a serious adverse event that could potentially be prevented or reduced in frequency or severity by appropriate use of a fluoroquinolone, patient selection, and careful monitoring. Therefore, FDA is notifying the makers of the fluoroquinolones of the need to add a Boxed Warning to the prescribing information for fluoroquinolones to highlight and strengthen the existing warning about the increased risk of fluoroquinolone-associated tendinitis and tendon rupture. FDA is also notifying the makers of fluoroquinolones of the need to develop and distribute a Medication Guide to alert patients about these possible side effects.

Id. In 2010, Relator alleges he met an individual who had been prescribed Levaquin and, as a result, "suffered severe neurological and psychiatric damage." (SAC ¶ 71). To investigate "the full extent of FQ side effects[,] . . . Relator formed the Southern Network on Adverse Reactions ('SONAR')" to conduct independent studies. (*Id.* ¶ 72). Relator's research allegedly found that as few as one to two doses of FQ could result in "devastating psychiatric and neurological side effects including but not limited to at least one of the following conditions: (1) anxiety, (2) loss of concentration, (3) depression, (4) insomnia, (5) panic attacks, (6) cognitive impairment, (7) depersonalization, (8) suicidal thoughts, (9) psychosis, (10) nightmares and/or abnormal dreams, (11) impaired memory, and/or other side effects." (*Id.* ¶ 73).

On April 17, 2013, Dr. Deborah Boxwell, an FDA official, conducted a study entitled "Department of Health and Human Services, Public Health Service, Food and Drug Administration, Center for Drug Evaluation and Research, Office of Surveillance and Epidemiology," subject line "Disabling Peripheral Neuropathy Associated with Systemic Fluoroquinolone Exposure." (*Id.* ¶ 75). To conduct the study, Dr. Boxwell relied on the FDA's reporting system of complaints concerning adverse drug reactions—the "FDA Adverse Event Reporting System" ("FAER"). (*Id.* ¶ 75 & 101). Dr. Boxwell found that 178 patients reported negative neurological and psychiatric side effects from FQ usage. (*Id.* ¶ 75). Dr. Boxwell's findings were allegedly "the very same side effects that Relator's patients had reported over the last five years and the very same side effects Relator's research had uncovered." (*Id.*). Dr. Boxwell named the neurological side effects and related psychiatric conditions "fluoroquinolones-associated disability" ("FQAD"). (*Id.*). "Dr. Boxwell's findings linked Defendants' drugs to mitochondrial toxicity and associated incurable neurodegenerative diseases." (*Id.*).

"On June 18, 2014, Relator filed a Citizen Petition [('Petition I')] with the FDA . . .based on Dr. Boxwell's findings." (*Id.* ¶ 76). In Petition I, Relator requested a review of FQ labeling to communicate the existence of possible mitochondrial toxicity. (*Id.*). On September 8, 2014, Relator filed another Citizen Petition ("Petition II") with the FDA informing the FDA of his research, including findings of "patients who suffered serious adverse psychiatric events—which were not listed by Defendants on the FQ labels." (*Id.* ¶ 77). In 2014, the FDA notified Relator that his submissions were received and his concerns would be reviewed. (*Id.* ¶ 78). In 2015, Relator discussed his research with television news outlets and senators of both major political parties. (*Id.* ¶ 79). "On November 5, 2015, Relator and Dr. Boxwell reported their findings" concerning FQ side effects "at an FDA Joint Meeting of the Antimicrobial Drugs Advisory Committee and the Drug Safety and Risk Management Advisory Committee." (*Id.* ¶ 85). Representatives for Defendants were present at this meeting. (*Id.*). "In February 2016, Dr. Bennett published his findings from his clinical studies and basic science research regarding the undisclosed side effects of FQs." (*Id.* ¶ 91).

On May 12, 2016, the FDA responded to Petition I, denying Relator's requests that:

> (1) language immediately be added to Levaquin's labeling regarding "Possible Mitochondrial Toxicity" in section 5 under the *Warnings and Precautions* heading;
>
> (2) a boxed warning immediately be added to Levaquin's labeling regarding "Possible Mitochondrial Toxicity"; and
>
> (3) Dear Health Care Provider (DHCP) letters be distributed regarding these labeling changes and that the letter request that physicians inform patients about the potential impact of "Possible Mitochondrial Toxicity" if the patients were previously prescribed this drug.

Letter from U.S. Food and Drug Admin., to Dr. Charles Bennett, M.D., PhD, MPP, Center Medication Safety and Efficacy, Final Response Petition Denial FDA-2014-P-0856 1 [hereinafter

Final Response Petition Denial FDA-2014-P-0856] (citations omitted) (citing Petition I at 1–2), https://www.regulations.gov/document/FDA-2014-P-0856-0011. The FDA thereby denied all of Relator's requests in Petition I. *Id.* The FDA, however, did state that it "[had] taken action to require certain changes to the labeling of Levaquin and other systemic fluoroquinolone antibacterial drugs to reflect new safety information." *Id.*; (SAC ¶ 92). Specifically, the FDA communicated that "in November 2015, [the] FDA held an Advisory Committee meeting to discuss the benefits and risks of systemic fluoroquinolone antibacterial drugs and . . . decided to require certain labeling changes for these drugs." Final Response Petition Denial FDA-2014-P-0856 at 13.

On July 26, 2016, the FDA published a news release sharing "that it had approved [] FQ labeling changes with enhanced warnings regarding disabling and potentially permanent side effects involving tendons, muscles, joints, nerves and the central nervous system." (SAC ¶ 94); News Release, U.S. Food and Drug Admin., FDA updates warnings for fluroquinolone antibiotics (July 26, 2016), https://www.fda.gov/news-events/press-announcements/fda-updates-warnings-fluoroquinolone-antibiotics. The FDA simultaneously published a Safety Announcement communicating the same information and providing that as a result of its findings, the FDA decided to "revise[] the *Boxed Warning*, FDA's strongest warning," and ultimately "determined that [FQs] should be reserved for use in patients who have no other treatment options for acute bacterial sinusitis, (ABS), acute bacterial exacerbation of chronic bronchitis (ABECB), and uncomplicated urinary tract infections (UTI) because the risk of these serious side effects generally outweighs the benefits in these patients. For some serious bacterial infections the benefits of fluoroquinolones outweigh the risks, and it is appropriate for them to remain available as a therapeutic option." *FDA Drug Safety Communication: FDA Updates Warnings for Oral and Injectable Fluoroquinolone*

Antibiotics Due to Disabling Side Effects, U.S. FOOD AND DRUG ADMIN. (Mar. 8, 2018), https://www.fda.gov/drugs/drug-safety-and-availability/fda-drug-safety-communication-fda-updates-warnings-oral-and-injectable-fluoroquinolone-antibiotics. The FDA did not require a warning about FQADs or the potential psychological adverse side effects that allegedly could result from the use of FQs. *Id.*

On July 10, 2018, the FDA issued a response to Petition II. (J&J Mov. Br. Ex. B). In the FDA's response, the FDA granted Relator's "request insofar as [] taking action to require certain changes to the labeling of levofloxacin products and other systemic fluoroquinolone antibacterial drugs to reflect new safety information." (*Id.* at 2). Specifically, the FDA granted Relator's request "to the extent that [the FDA] separated psychiatric adverse reactions from other central nervous system adverse reactions in the labeling." (*Id.* at 11). Petition II was otherwise denied. (*Id.* at 12). Additionally, the FDA disagreed with Relator's characterization of "psychiatric adverse events," determining that "loss of consciousness," "depressed level of consciousness," and "coma" "are better characterized as central nervous system disorders." (*Id.* at 1 n.2). The term "feeling abnormal" was written off by the FDA as neither a central nervous system disorder nor a psychiatric event. (*Id.*). Moreover, the FDA clarified that despite Relator's claims alleging that Levaquin is still in use, "[a]ll Levaquin products [were] discontinued from sale." (*Id.* at 1 n.1); *see also* 85 Fed. Reg. 83973–75 (Dec. 23, 2020); 82 Fed. Reg. 28322–29 (June 21, 2017). After the publication of the FDA's letter, the FDA recognized that Levaquin's withdrawal from sale was not done for reasons of safety or effectiveness. 86 Fed. Reg. 58674–75 (Oct. 25, 2021).

On June 20, 2019, Relator filed another request that the FDA require changes to the labeling of Levaquin. (Bayer Mov. Br. at 8 (citing Ex. K)). Specifically, Relator requested that the FDA require a risk evaluation and mitigation strategy for Levaquin. (*Id.*) In August 2020, the

FDA denied Relator's request, noting that the serious risks associated with Levaquin, were "adequately communicated in Levaquin's approved labeling." (*Id.* Ex. L at 7). In the FDA's denial, they once again reiterated that "[a]ll Levaquin products are currently discontinued from sale." (*Id.* at 1 n.1). Additionally, the FDA explained that FQAD "is not [an] accepted medical terminology and is not used in clinical practice." (*Id.* at 1 n.2). The FDA also interpreted Relator's use of "'FQAD' to refer to the disabling and potentially irreversible serious adverse reactions in different body systems that can occur together in the same patient with fluoroquinolone use and as described in the Boxed Warning, the WARNINGS AND PRECAUTIONS, and the PATIENT COUNSELING INFORMATION sections of the labeling." (*Id.*).

B. Procedural History

On June 9, 2017, Relator filed this *qui tam* action under seal, naming Bayer Corporation as the only Defendant. (D.E. No. 1). On August 10, 2018, Relator filed the First Amended Complaint, asserting claims under (i) the FCA and (ii) state law. (D.E. No. 6). On July 28, 2020, the United States filed its Notice to Decline to Intervene pursuant to 31 U.S.C. § 3730(b)(4)(B). (D.E. No. 8). On March 11, 2021, Defendants separately moved to dismiss the First Amended Complaint. (D.E. Nos. 38 & 41). On March 31, 2022, this Court granted dismissal of the First Amended Complaint without prejudice. (D.E. No. 56 ("*Bennett I*")). Specifically, this Court found that Relator failed to plead a necessary element of his FCA claim, falsity, because (i) Relator failed to distinguish between Bayer and J&J, (ii) "the Amended Complaint failed to allege what Bayer and J&J actually said about Cipro, Levaquin, and the adverse effects of both," and (iii) "Relator [did] not allege what specific information Bayer and J&J failed to disclose and why they were under a duty to disclose that information even though [] the FDA was made aware of all the information put forth in the Amended Complaint." (*Bennett I* at 11–15). Moreover, the Court also

held that Relator failed to sufficiently allege another necessary element of his FCA claim, materiality, because "[t]he Amended Complaint [did] not identify any information concerning the safety of Cipro and Levaquin that the FDA was unaware of." (*Id.* at 19). This Court also found that Relator failed to satisfy Rule 9(b)'s particularity requirement when asserting "allegations concerning J&J promoting off-label use of Levaquin." (*Id.* at 23). Lastly, as a result of the dismissal of the federal FCA claims, this Court declined to exercise supplemental jurisdiction over the state law claims. (*Id.* at 23–24).

On May 31, 2022, Relator filed the Second Amended Complaint. (SAC). On October 31, 2022, J&J and Bayer moved separately to dismiss the Second Amended Complaint. (J&J Mov. Br.; Bayer Mov. Br.). The Motions were fully briefed at the time of filing. (J&J Mov. Br.; D.E. No. 69 ("J&J Opp. Br."); D.E. No. 70 ("J&J Reply"); Bayer Mov. Br.; D.E. No. 72 ("Bayer Opp. Br."); D.E. No. 73 ("Bayer Reply")).

On May 17, 2023, Magistrate Judge James B. Clark appointed mediator Robert G. Marasco and ordered the parties to complete mediation on or before August 31, 2023. (D.E. No. 75). "Pending the completion of mediation, the action and [the] pending [Motions to Dismiss the Second Amended Complaint were] . . . administratively terminated." (*Id.* at 1). On August 30, 2023, the Parties submitted a letter informing the Court that "the mediation conducted on August 10, 2023, before the court-appointed mediator . . . did not result in a settlement." (D.E. No. 82). On August 30, 2023, J&J filed a Notice to Reinstate the Motion to Dismiss Relator's Second Amended Complaint. (D.E. No. 83). On August 31, 2023, Bayer filed its Notice to Reinstate the Motion to Dismiss Relator's Second Amended Complaint. (D.E. No. 84). Judge Clark restored the matter to the active docket on September 5, 2023. (D.E. No. 85). On September 8, 2023, and then again—at the request of the Court for clarification—on March 4, 2024, Relator filed a letter

informing the Court that in opposition to the reinstated Motions to Dismiss, Relator would rely on his previously filed oppositions on the docket. (D.E. No. 86 & 89; *see generally* J&J Opp. Br.; Bayer Opp. Br.).

II. LEGAL STANDARD

In assessing whether a complaint states a cause of action sufficient to survive dismissal under Rule 12(b)(6), the Court accepts "all well-pleaded allegations as true and draw[s] all reasonable inferences in favor of the plaintiff." *City of Cambridge Ret. Sys. v. Altisource Asset Mgmt. Corp.*, 908 F.3d 872, 878 (3d Cir. 2018). "[T]hreadbare recitals of the elements of a cause of action, legal conclusions, and conclusory statements" are all disregarded. *Id.* at 878–79 (internal quotation marks omitted) (quoting *James v. City of Wilkes-Barre*, 700 F.3d 675, 681 (3d Cir. 2012)). The complaint must "contain sufficient factual matter, accepted as true, to state a claim to relief that is plausible on its face," and a claim is facially plausible when the plaintiff "pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Zuber v. Boscov's*, 871 F.3d 255, 258 (3d Cir. 2017) (internal quotation marks omitted) (first quoting *Santiago v. Warminster Twp.*, 629 F.3d 121, 128 (3d Cir. 2010); and then quoting *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009)).

Although the Court is generally confined to the allegations in the pleadings in ruling on a motion to dismiss under Rule 12(b)(6), it may, without converting the motion to one for summary judgment, consider a document "*integral to or explicitly relied* upon in the complaint," as well as "an undisputedly authentic document that a defendant attaches as an exhibit to a motion to dismiss if the plaintiff's claims are based on the document." *In re Burlington Coat Factory Sec. Litig.*, 114 F.3d 1410, 1426 (3d Cir. 1997) (internal quotation marks omitted) (first quoting *Shaw v. Digit. Equip. Corp.*, 82 F.3d 1194, 1220 (1st Cir. 1996); and then quoting *In re Donald J. Trump Casino*

Sec. Litig., 7 F.3d 357, 368 n.9 (3d Cir. 1993)); *see also Lum v. Bank of Am.*, 361 F.3d 217, 221 n.3 (3d Cir. 2004) ("In deciding motions to dismiss pursuant to Rule 12(b)(6), courts generally consider only the allegations in the complaint, exhibits attached to the complaint, matters of public record, and documents that form the basis of a claim.").

When asserting an FCA claim, in addition to the pleading standards identified under Rule 12(b)(6), "plaintiffs must [also] plead FCA claims with particularity in accordance with Rule 9(b)." *U.S. ex rel. Wilkins v. United Health Grp., Inc.*, 659 F.3d 295, 301 (3d Cir. 2011), *abrogated on other grounds as recognized in United States ex rel. Freedom Unlimited, Inc. v. City of Pittsburgh, Pennsylvania*, 728 F. App'x 101, 106 (3d Cir. 2018). Under Rule 9(b), "a party must state with particularity the circumstances constituting fraud or mistake," but "[m]alice, intent, knowledge, and other conditions of a person's mind may be alleged generally." Fed. R. Civ. P. 9(b). In the context of the FCA, a plaintiff need not plead representative samples of fraudulent claims submitted to the Government. *Foglia v. Renal Ventures Mgmt., LLC*, 754 F.3d 153, 155–57 (3d Cir. 2014). Nor must a plaintiff "identify a specific claim for payment at the pleading stage of the case to state a claim for relief." *United States ex rel. Wilkins*, 659 F.3d at 308. Instead, it is enough for a plaintiff to allege the "particular details of a scheme to submit false claims paired with reliable indicia that lead to a strong inference that claims were actually submitted." *Foglia*, 754 F.3d at 156, 158 (internal quotation marks omitted) (quoting *United States ex rel. Grubbs v. Kanneganti*, 565 F.3d 180, 190 (5th Cir. 2009)). "Describing a mere opportunity for fraud will not suffice." *Id.* at 158. Thus, "an inference of illegality based on facts that could plausibly have either a legal or illegal explanation [is] insufficient to meet Rule 9(b)'s burden, because a relator must 'establish a "strong inference" that false claims were submitted' and the possibility of a legitimate

explanation undermines the strength of the inference of illegality." *United States v. Omnicare, Inc.*, 903 F.3d 78, 92 (3d Cir. 2018) (quoting *Foglia*, 754 F.3d at 158).

III. DISCUSSION

"Enacted in 1863, the False Claims Act 'was originally aimed principally at stopping the massive frauds perpetrated by large contractors during the Civil War.'" *Universal Health Servs., Inc. v. United States ex rel. Escobar*, 579 U.S. 176, 181 (2016) (quoting *United States v. Bornstein*, 423 U.S. 303, 309 (1976)). Today, the FCA is not limited to its original principal aim. *Id.* at 182. Congress, since the enactment of the FCA, "has repeatedly amended the Act." *Id.* Still, the FCA's "focus remains on those who present or directly induce the submission of false or fraudulent claims" to the Government for payment. *Id.* To that end, the FCA "enables individuals, known as Relators, to bring enforcement actions, known as *qui tam* actions, on behalf of the United States to recover funds which were fraudulently obtained, and to share in any resulting damages award." *United States ex rel. Dhillon v. Endo Pharms.*, 617 F. App'x 208, 211 (3d Cir. 2015).

The FCA holds any person liable to the United States who:

> (A) knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval;
>
> (B) knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim;
>
> (C) conspires to commit a violation of subparagraph (A), (B) . . . .

31 U.S.C.A. § 3729(a)(1)(A)–(C). Thus, an FCA violation "includes four elements: falsity, causation, knowledge, and materiality." *United States ex rel. Petratos v. Genentech Inc.*, 855 F.3d 481, 487 (3d Cir. 2017). Even if the FCA's elements are adequately pled, the FCA prohibits some claims based on the "public disclosure bar," *Graham Cnty. Soil & Water Conservation Dist. v.*

United States ex rel. Wilson, 559 U.S. 280, 295 (2010), and the "first-to-file bar," *Kellogg Brown & Root Servs., Inc. v. United States ex rel. Carter*, 575 U.S. 650, 662 (2015).[3]

A. Federal False Claims Act

i. Falsity

An actionable claim can "be factually or legally false." *Petratos*, 855 F.3d at 486 n.1. "A claim is *factually false* when the claimant misrepresents what goods or services that it provided to the Government[,] and a claim is *legally false* when the claimant knowingly falsely certifies that it has complied with a statute or regulation [in which] compliance [] is a condition for Government payment." *U.S. ex rel. Wilkins*, 659 F.3d at 305 (emphasis added). A relator may also pursue a fraudulent inducement theory of liability. *United States ex rel. Thomas v. Siemens AG*, 593 F. App'x 139, 143 (3d Cir. 2014). "Although the focus of the False Claims Act is on false 'claims,' courts have employed a fraudulent inducement theory to establish liability under the Act for each claim submitted to the government under a contract which was procured by fraud, even in the absence of evidence that the claims were fraudulent in themselves." *Id.* Thus, under a fraudulent inducement theory, even though a claim paid under a contract is "not literally false," the claim may become an actionable false claim if the paid claim arises from an "original fraudulent misrepresentation." *United States ex rel. Brown v. Pfizer, Inc.*, No. 05-6795, 2017 WL 1344365, at *9 (E.D. Pa. Apr. 12, 2017) (quoting *United States ex rel. Longhi v. Lithium Power Techs., Inc.*, 575 F.3d 458, 468 (5th Cir. 2009)). "To prevail on a fraudulent inducement claim under the False Claims Act, a plaintiff must show that (1) there was a knowingly false or fraudulent statement; (2) that the statement was material; and (3) that it caused the government to pay out money or to forfeit

[3] Both Bayer and J&J argue that the public disclosure bar exception applies here and warrants dismissal of Relator's Second Amended Complaint. (Bayer Mov. Br. at 24–29; J&J Mov. Br. at 26–29). Because, as described below, the Second Amended Complaint fails to plausibly plead the elements of an FCA claim, the Court declines to consider Defendants' arguments regarding the public disclosure bar.

moneys due (i.e., a "claim")." *U.S. ex rel. Thomas v. Siemens AG*, 593 F. App'x 139, 143 (3d Cir. 2014) (citations omitted).

With regards to the first element, Relator contends that Defendants made knowingly false or fraudulent statements when they "willfully concealed the existence, frequency, and severity of dangerous, debilitating, and permanent side effects of FQs" (SAC ¶¶ 3–10) and "intentionally disaggregated individual symptomatic components of serious multi-system syndromes in [the] NDA[s] submitted to the FDA." (*Id.* ¶¶ 57 & 59). Specifically, Relator argues that Bayer and J&J fraudulently induced the FDA to approve their NDAs by disaggregating individual symptomatic components of serious multi-system syndromes in their respective NDAs. (*Id.*). Relator further claims that "Defendants failed to conduct appropriate follow-up studies, surveys, or inquires among clinical subjects, thereby intentionally failing to evaluate the long-term side effects of FQ use." (SAC ¶ 68). Consistent with these claims, Relator accuses J&J of intentionally masking the "true frequency and severity of neurological and psychiatric adverse events" in J&J's NDA to "intentionally mislead the FDA." (*Id.* ¶¶ 69 & 89). In doing so, Relator argues, Defendants were able to hide the "neurological and psychiatric side effects of [Cipro and Levaquin] in plain sight." (*Id.*). As a result of Defendants' omissions, Defendants were allegedly able to fraudulently "gain and keep FDA approval and favorable safety labeling." (*Id.* ¶ 8).

Bayer and J&J argue that the Second Amended Complaint should be dismissed because Relator's fraudulent inducement theory of liability fails to sufficiently plead falsity. (Bayer Opp. Br. at 19); (J&J Opp. Br. at 16). Bayer and J&J each argue separately that Relator's new theory of liability is not legally viable in this matter. (Bayer Mov. Br. at 18 & 19; J&J Mov. Br. at 13–16).

In Bayer's Moving Brief, Bayer contends that Relator's falsity argument constitutes a fraudulent inducement theory, and that "[t]he Third Circuit has not recognized a fraudulent inducement theory under the FCA in the absence of a direct contractual relationship between the defendant and the government." (Bayer Mov. Br. at 18). In support of this position, Bayer cites *In re Plavix Mktg., Sales Prac. & Prod. Liab. Litig. (No. II)*, 332 F. Supp. 3d 927, 952 (D.N.J. 2017), a recent decision in this District where the court refused to extend a fraudulent inducement theory of liability under the FCA to "non-contract interactions with government regulatory bodies." (Bayer Mov. Br. at 18 (citing *Plavix*, 332 F. Supp. 3d at 953)). Bayer also argues that "Relator has not plausibly pled—let alone pled with sufficient particularity that Bayer or Merk made *any* initial false representation to [the] FDA to get Cipro approved." (Bayer Mov. Br. at 20).

Similarly, J&J argues that Relator's theory of liability can be characterized as a "fraud-on-the-FDA" theory of liability, which must in fact be reliant on a contractual relationship. (*Id.* at 13). This theory of liability, J&J claims, is "an inappropriate and extra-statutory expansion of FCA liability." (*Id.*). J&J goes on to warn the Court that acceptance of Relator's theory of liability "risks far-reaching collateral effects," exceeding the "the bounds of the FCA's statutory language and intended scope." (*Id.* at 14). Furthermore, J&J states that this theory of liability could disrupt the FCA's statute of limitations, which may "lead to an indefinite window of exposure in which liability could attach decades later." (*Id.* at 14). J&J's Reply clarifies that its argument is not that Relator is required to plead that J&J had a contract with the FDA through misrepresentation, but instead "that the fraudulent inducement theory does not apply here because Relator does not plead that J&J's alleged false statements *induced any contract* under which false claims were submitted." (J&J Reply at 2). J&J further argues that the "'disaggregation' allegations notably do not assert that J&J either omitted data from, or provided factually false data regarding, side effects to the

FDA in its NDA." (J&J Mov. Br. at 17). "Additionally, Relator does not allege J&J's failure to 'aggregate' the individual side effects violates any FDA regulations concerning how applications should present data in an NDA." (*Id.*).

In Relator's opposition to J&J's moving brief, Relator contends that

> J&J's argument requires factual determinations as to what J&J knew and conveyed, what the FDA knew and/or asked for, and/or what the effect of the manipulated data was. These are all issues of fact that cannot be resolved at the pleading stage. J&J also asserts that it had no obligation to present its data in any certain way. However, even in the absence a specific regulator[y] violation, it is still fraudulent to manipulate data that is intended to mislead and does in fact mislead the FDA.

(J&J Opp. Br. at 20). Relator further alleges that a fraudulent inducement theory does not "necessarily require a contractual relationship between the government and the party alleged to have engaged in the fraudulent inducement." (Bayer Opp. Br. at 13) (citing citations omitted*)*. Relator also rebuts J&J's arguments regarding a "fraud-on-the-FDA" theory of liability by asserting that "[n]o Circuit has foreclosed the fraud-on-the-market (or FDA) theory on the facts presented here." (J&J Opp. Br. at 16).

The Court agrees with Defendants: Relator has failed to sufficiently plead falsity. First, Relator fails to demonstrate that any contractual relationship exists as a result of the alleged false or fraudulent statements. As Defendants point out, the Third Circuit has only applied the fraudulent inducement theory of liability under the FCA in the context of *contracts* that have been *induced* by fraud. *Plavix*, 332 F. Supp. at 952 (citation omitted). In line with other courts in this district, "[i]n the absence of any binding or persuasive authority suggesting that a theory of liability formed in the context of contracts should be applied equally in the context of non-contract interactions with government regulatory bodies, as in this case, [], this Court will not" exceed the boundaries established by the Third Circuit. *Plavix*, 332 F. Supp. at 952. As such, this Court will

not permit a fraudulent inducement claim in the context of a non-contractual interaction with the FDA, and therefore declines to find that a theory of liability premised on "fraud-on-the-FDA" is a viable claim applicable to the facts before the Court in this matter. Because fraudulent inducement is Relator's only proffered theory for falsity, Relator has therefore failed to plead falsity.

Even if the Court were to find that a fraudulent inducement claim could exist in the context of a non-contractual interaction with the FDA, Relator nevertheless fails to establish a "strong inference" that Defendants misrepresented or omitted any required disclosures, or, that any false or fraudulent statements were knowingly made by Bayer or J&J to the FDA to get Cipro or Levaquin approved. Here, Relator understands that an NDA requires disclosure of

> the physical and chemical characteristics of the drug substance; studies of the toxicological effects of the drug (including of acute, subacute, and chronic toxicity); a comparison of toxicology data from animal and human studies; for anti-infective drugs, a description of the biochemical basis of the drug's action on microbial physiology; and safety update reports from human and animal studies that includes information about each patient who may have died during the study or did not complete the study because of adverse events.

(SAC ¶ 53). Additionally, Relator himself notes that the

> [T]he FDA has a carefully delineated Drug Approval Process, conducted by the agency's Center for Drug Evaluation and Research ("CDER"). The purpose [of the] FDA review process is to "(a) Facilitate the approval of drugs shown to be safe and effective; and (b) ensure the disapproval of drugs not shown to be safe and effective." 21 C.F.R. § 314.2. Approval of the drug by the FDA is the final step in a multi-year process of study and testing.

(*Id.* ¶ 51). Nonetheless, Relator alleges that

> Defendants knew and intentionally failed to accurately and fully disclose the adverse side effects of their FQs by telling a series of half-truths, manipulating clinical trials, disaggregation of adverse effects they knew to be directly connected; and denying the existence, frequency, and severity of the side effects, and thereby continued to falsely represent the safety of FQs to the FDA, patients,

> and the market at large in order to continue turning billions of dollars in profits from their potentially dangerous drugs.

(SAC ¶ 108).

However, "[t]here can only be liability under the False Claims Act where the defendant has an obligation to disclose omitted information," and the Court finds that there is no indication that Defendants did not comply with the NDA approval process or omitted information specifically requested by the FDA. *Bennett I, 2022 WL 970219*, at *8 (quoting *United States ex rel. Berge v. Bd. of Trustees of Univ. of Ala.*, 104 F.3d 1453, 1461 (4th Cir. 1997)). Additionally, Relator's numerous Citizen Petitions and FDA responses, demonstrate that the FDA was made aware of all the information put forth in the Second Amended Complaint. *Id.* (quoting *U.S. ex rel. Harman v. Trinity Indus. Inc.*, 872 F.3d 645, 667 n.90 (5th Cir. 2017) (citing 31 U.S.C. § 3729). Lastly, the FCA "does not contain an independent duty to disclose certain information," and Defendants seemingly fulfilled all required disclosures to obtain NDA approval from the FDA. *Harman*, 872 F.3d at 667 n.90 (citing 31 U.S.C. § 3729). Therefore, the Court finds that Relator's FCA claim fails because Relator insufficiently plead falsity.[4]

B. State Claims

Relator invokes jurisdiction over state law claims pursuant to 31 U.S.C. § 3732(b). (SAC ¶ 21). That section provides, "[t]he district courts shall have jurisdiction over any action brought under the laws of any State for the recovery of funds paid by a State or local government if the action arises from the same transaction or occurrence as an action brought under section 3730." § 3732(b). There now being no surviving federal FCA claim, the Court declines to exercise supplemental jurisdiction over the state law claims. *See United States ex rel. Mohajer v. Omnicare,*

[4] Because Relator fails to plead falsity, the Court declines to address Defendants' arguments related to causation, knowledge, and materiality.

Inc., 525 F. Supp. 3d 447, 461 (S.D.N.Y. 2021); *United States ex rel. LaFauci v. AbbVie Inc.*, No. 15-7931, 2019 WL 1450791, at *5 (D.N.J. Apr. 2, 2019).

C. CONCLUSION

Based on the foregoing, Defendants' Motions (D.E. Nos. 83 & 84) are **GRANTED**. Denial of leave to amend is warranted in cases of "undue delay, bad faith or dilatory motive . . . , repeated failure to cure deficiencies by amendments previously allowed, undue prejudice to the opposing party by virtue of allowance of the amendment, [and] futility of amendment." *Great W. Mining & Min. Co. v. Fox Rothschild LLP*, 615 F.3d 159, 174 (3d Cir. 2010) (quoting *Foman v. Davis*, 371 U.S. 178, 182 (1962)). Because an additional amendment would be futile, the Second Amended Complaint is dismissed *with prejudice*. An appropriate Order follows.

s/ Esther Salas

Dated: April 4, 2024 **Hon. Esther Salas, U.S.D.J.**